

DIABETES RESEARCH IN CHILDREN NETWORK (DirecNet)

Description of Project

- The mission of DirecNet is to investigate the potential use of glucose monitoring technology and its impact on the management of type 1 diabetes (T1DM) in children.

Accomplishments

DirecNet has developed five primary protocols and three ancillary studies.

Completed Protocols

- 1) The Accuracy of Continuous Glucose Monitors in Children with Type 1 Diabetes; this protocol included three ancillary studies:
 - a. An assessment of the accuracy of the OneTouch Ultra home glucose meter;
 - b. An evaluation of the alarm function of the GlucoWatch 2 Biographer;
 - c. An evaluation of an accelerometer to assess exercise in children with T1DM.
- 2) A Pilot Study to Assess the Accuracy of Continuous Glucose Monitors in Normal Children
- 3) A Pilot Study to Evaluate the GlucoWatch 2 Biographer in the Management of Type 1 Diabetes in Children

Protocols In Progress

- 1) A Randomized Clinical Trial to Assess the Effectiveness of the GlucoWatch Biographer in the Management of Type 1 Diabetes in Children

Protocols Pending Initiation

- 1) The Effect of Exercise on the Development of Hypoglycemia in Children with Type 1 Diabetes

Manuscripts, Abstracts, and Presentations

Manuscripts - Published

- 1) The Diabetes Research in Children Network (DirecNet) Study Group: **The Accuracy of the CGMS™ in Children with Type 1 Diabetes: Results of the Diabetes Research in Children Network (DirecNet) Accuracy Study.** Diabetes Technol Ther 2003; 5(5): 781-789.
- 2) The Diabetes Research in Children Network (DirecNet) Study Group: **The Accuracy of the GlucoWatch® G2™ Biographer in Children with Type 1 Diabetes: Results of the Diabetes Research in Children Network (DirecNet) Accuracy Study.** Diabetes Technol Ther 2003; 5(5): 791-800.
- 3) The Diabetes Research in Children Network (DirecNet) Study Group: **A Multi-center Study of the Accuracy of the One Touch® Ultra® Home Glucose Meter in Children with Type 1 Diabetes.** Diabetes Technol Ther 2003; 5(6): 933-941.

- 4) Diabetes Research in Children Network (DirecNet) Study Group: **Accuracy of the GlucoWatch G2 Biographer and the Continuous Glucose Monitoring System During Hypoglycemia. Experience of the Diabetes Research in Children Network (DirecNet).** *Diabetes Care* 2004; 27(3): 722-726

Manuscripts - In Press

- 5) Diabetes Research in Children Network (DirecNet) Study Group: **Accuracy of Continuous Glucose Sensors in Healthy, Nondiabetic Children. Results of the Diabetes Research in Children Network (DirecNet) Accuracy Study.** *Journal of Pediatrics*, accepted for publication, April 2004.

Manuscripts - Submitted

- 6) Diabetes Research in Children Network (DirecNet) Study Group: **GlucoWatch® G2™ Biographer (GW2B) Alarm Reliability During Hypoglycemia in Children.** *Diabetes Technol Ther*, submitted for publication, February 2004.
- 7) Diabetes Research in Children Network (DirecNet) Study Group: **Comparison of Hemoglobin A_{1c} levels assayed by DCA2000 and the DCCT/EDIC Central Laboratory: a Diabetes Research in Children Network (DirecNet) Study.** *Diabetes Care*, submitted for publication, April 2004.

Manuscripts - In Preparation

- 8) Diabetes Research in Children Network (DirecNet) Study Group: **Accuracy of the Modified Continuous Glucose Monitoring System (CGMS®) Sensor in an Outpatient Setting: Results from a Diabetes Research in Children Network (DirecNet) Study**
- 9) Diabetes Research in Children Network (DirecNet) Study Group: **Diabetes Self Management Profile for Conventional and Flexible Regimens: Cross-Sectional and Longitudinal Analysis of Psychometric Properties**
- 10) Diabetes Research in Children Network (DirecNet) Study Group: **Eight-point testing versus the Continuous Glucose Monitoring System in evaluation of glycemic control in children with type 1 diabetes**

Published Abstracts

- 1) Nelly Mauras, Roy Beck, Katrina Ruedy, Andrea Booth, Stuart Weinzimer, and the Diabetes Research in Children Network (DirecNet) Study Group: **The Physiological Variations of Plasma Glucose Concentrations in Healthy, Non-Diabetic Children: Use of Continuous Glucose Sensors.** *Pediatr Res* 2003 Apr;53(4Pt 2):1A-669A (Oral Presentation at 2003 PAS Meeting)
- 2) Stuart Weinzimer, Roy Beck, Katrina Ruedy, Andrea Booth, Elizabeth Boland, and the Diabetes Research in Children Network (DirecNet) Study Group: **Mealtime Glycemic Excursions in Pediatric Subjects with Type 1 Diabetes Mellitus (T1DM): The DirecNet Experience.** *Pediatr Res* 2003 Apr;53(4Pt 2):1A-669A (Poster Presentation at 2003 PAS Meeting)

- 3) Eva Tsalikian, Roy Beck, Katrina Ruedy, Andrea Booth, Michael Tansey, and the Diabetes Research in Children Network (DirecNet) Study Group: **Glycemic Pattern of Insulin Induced Hypoglycemia in Pediatric Subjects with Type 1 Diabetes Mellitus (T1DM): The DirecNet Experience.** *Pediatr Res* 2003 Apr;53(4Pt 2):1A-669A (Poster Presentation at 2003 PAS Meeting)

- 4) Bruce Buckingham, Roy Beck, William Tamborlane, Katrina Ruedy, Elizabeth Boland, Peter Chase, Timothy Wysocki, Eva Tsalikian, Darrell Wilson, Nelly Mauras, Stuart Weinzimer, Michael Tansey, Rosanna Fiallo-Scharer, Andrea Booth, Craig Kollman and the Diabetes Research In Children Network (DirecNet) Study Group: **Diabetes Research in Children Network (DirecNet) Accuracy Study of the Continuous Glucose Monitoring System (CGMS) and GlucoWatch® G2™ Biographer (GWB) in Children with Type 1 Diabetes-A CRC-based Study.** *Diabetes*. 2003 Jun;52 Suppl 1:A36. (Oral Presentation at 2003 ADA Meeting)

- 5) Darrell Wilson, Bruce Buckingham, Roy Beck, Katrina Ruedy, Craig Kollman, Eva Tsalikian, Timothy Wysocki, Stuart Weinzimer, Peter Chase and the Diabetes Research in Children Network (DirecNet) Study Group: **A 5-center CRC-based Study of the Accuracy of the GlucoWatch®G2™ Biographer in Children and Adolescents with Type 1 Diabetes.** *Diabetes*. 2003 Jun;52 Suppl 1:A101. (Poster Presentation at 2003 ADA Meeting)

- 6) Rosanna Fiallo-Scharer, Peter Chase, Roy Beck, Katrina Ruedy, Andrea Booth, Timothy Wysocki, Elizabeth Boland, Bruce Buckingham, Eva Tsalikian and the Diabetes Research In Children Network (DirecNet) Study Group: **Performance of the One Touch Ultra at Different Glucose Levels in Three Age Groups of Children with T1DM in the CRC-DirecNet Accuracy Study.** *Diabetes*. 2003 Jun;52 Suppl 1:A562. (Poster Presentation at 2003 ADA Meeting)

- 7) Elizabeth Boland, Stuart Weinzimer, Roy Beck, Katrina Ruedy, Craig Kollman, Bruce Buckingham, Peter Chase, Michael Tansey, Nelly Mauras and the Diabetes Research In Children Network (DirecNet) Study Group: **Performance of the Medtronic MiniMed Continuous Glucose Monitoring System (CGMS) in Children with T1DM in the DirecNet Accuracy Study.** *Diabetes*. 2003 Jun;52 Suppl 1:A90. (Poster Presentation at 2003 ADA Meeting)

- 8) Michael Tansey, Roy Beck, Bruce Buckingham, Nelly Mauras, Rosanna Fiallo-Scharer, Dongyuan Xing, William Tamborlane, Katrina Ruedy, and the Diabetes Research in Children Network (DirecNet) Study Group. **A Comparison of the Original vs. Modified Continuous Glucose Monitoring System (CGMS™) Sensor During Hypoglycemia in the Diabetes Research in Children Network (DirecNet) Accuracy Study.** *Diabetes Technology and Therapeutics Meeting*, November 7-8, 2003- San Francisco, California. (Poster Presentation at 2003 DTT Meeting)

- 9) Craig Kollman, Darrell Wilson, Tim Wysocki, Rosanna Fiallo-Scharer, Eva Tsalikian, William Tamborlane, Roy Beck, Katrina Ruedy, and the Diabetes Research In Children Network (DirecNet) Study Group. **Limitations of Statistical Measures of Error in**

Assessing the Accuracy of Glucose Sensors. Diabetes Technology and Therapeutics Meeting, November 7-8, 2003- San Francisco, California. (Oral and Poster Presentations at 2003 DTT Meeting)

- 10) Eva Tsalikian, Craig Kollman, Rosanna Fiallo-Scharer, Roy Beck, Bruce Buckingham, Nelly Mauras, Stuart Weinzimer, William Tamborlane, Katrina Ruedy, and the Diabetes Research In Children Network (DirecNet) Study Group. **Down Alert Function of the GlucoWatch® G2™ Biographer (GW2B) During Insulin-induced Hypoglycemia in Children.** Diabetes Technology and Therapeutics Meeting, November 7-8, 2003- San Francisco, California. (Poster Presentation at 2003 DTT Meeting)
- 11) Stuart Weinzimer, Katrina Ruedy, Jennifer Fisher, Linda Larson, Jennifer Block, Elizabeth Boland, Keisha Bird, and the Diabetes Research in Children Network (DirecNet) Study Group. **Diabetes Research in Children Network (DirecNet) Outpatient Pilot Study to Evaluate the GlucoWatch® G2™ Biographer (GW2B) in the Management of Type 1 Diabetes (T1DM) in Children.** Diabetes Technology and Therapeutics Meeting, November 7-8, 2003- San Francisco, California. (Poster Presentation at 2003 DTT Meeting)

Submitted Abstracts

- 12) William Tamborlane, Dongyuan Xing, Michael Steffes, Craig Kollman, Katrina Ruedy, Roy Beck, Rosanna Fiallo-Scharer, Larry Fox, Darrell Wilson, Eva Tsalikian, and the Diabetes Research In Children Network (DirecNet) Study Group. **Performance of the DCA2000 for Measurement of Hemoglobin A1c Levels in Children with T1DM in a DirecNet Outpatient Clinical Trial.** Accepted as Poster Presentations for 2004 Pediatric Academic Societies' Annual Meeting.
- 13) Stuart Weinzimer, Katrina Ruedy, Linda Larson, Jennifer Block, Jennifer Fisher, Elizabeth Doyle, Keisha Bird, and the Diabetes Research in Children Network (DirecNet) Study Group. **Diabetes Research in Children Network (DirecNet) Outpatient Pilot Study to Evaluate the Feasibility of Computer-Based Data Acquisition and Transmission.** Accepted as Poster Presentation for 2004 Pediatric Academic Societies' Annual Meeting.
- 14) Michael Tansey, Roy Beck, Bruce Buckingham, Nelly Mauras, Rosanna Fiallo-Scharer, Dongyuan Xing, Craig Kollman, William Tamborlane, Katrina Ruedy, and the Diabetes Research in Children Network (DirecNet) Study Group. **A Comparison of the Original vs. Modified Continuous Glucose Monitoring System (CGMS™) Sensor During Using Data from Two DirecNet Studies.** Accepted for 2004 American Diabetes Association Annual Meeting.
- 15) Rosanna Fiallo-Scharer, Dongyuan Xing, Stuart Weinzimer, Bruce Buckingham, Nelly Mauras, Michael Tansey, Roy Beck, Katrina Ruedy, Craig Kollman, William Tamborlane, and the Diabetes Research in Children Network (DirecNet) Study Group. **Utility of CGMS as a Measure of Glycemic Control in Children with Type 1 Diabetes (T1DM).** Accepted as Oral Presentation for 2004 American Diabetes Association Annual Meeting.

- 16) Peter Chase, Dongyuan Xing, Stuart Weinzimer, Bruce Buckingham, Nelly Mauras, Michael Tansey, Roy Beck, Katrina Ruedy, Craig Kollman, William Tamborlane, and the Diabetes Research in Children Network (DirecNet) Study Group. **Comparison of 8-point Glucose Testing with Glycemic Control in Children with Type 1 Diabetes (T1DM).** Accepted for 2004 American Diabetes Association Annual Meeting.
- 17) Tim Wysocki, Dongyuan Xing, Rosanna Fiallo-Scharer, Elizabeth Doyle, Jennifer Block, Eva Tsalikian, Roy Beck, Katrina Ruedy, Craig Kollman, William Tamborlane, and the Diabetes Research in Children Network (DirecNet) Study Group. **Diabetes Self-Management Profile-Revised for Conventional and Flexible Insulin Regimens.** Accepted as Poster Presentation for 2004 American Diabetes Association Annual Meeting.

Additional Accomplishments

- Development of methods for the use of personal computers in the home for the child and family to download continuous glucose monitoring devices and home glucose meters.
- Development of methods for the data management and analysis of continuous glucose monitoring data and for utilizing the data in the management of children with T1DM.
- Development of methods for use of tablet computers in the clinic for paperless case report form completion and for completion of quality of life questionnaires.
- Development of a quality of life questionnaire related to use of continuous glucose monitors.

Future directions

- Develop and initiate one new randomized trial and/or observational study each year.
- Assess the accuracy of continuous monitoring devices in order to determine if these devices are useful in improving glycemic control and preventing hypoglycemia in children with T1DM.
- Determine the optimal utilization of continuous glucose monitors in the management of T1DM in children.
- Assess the impact of continuous glucose monitoring on quality of life for the child and family.
- Develop tools for the child and parents to use for incorporating continuous glucose monitors into diabetes self-management.
- Assess possible changes in neurocognitive function and how it relates to frequency of hypoglycemia in young children with type 1 diabetes.
- Evaluate and develop distinct, age-appropriate treatment approaches to T1DM in children.
- Use continuous glucose monitoring to characterize the glycemic profile of nondiabetic children.

Participants

Sponsors: National Institute of Child Health and Human Development
 National Institute of Diabetes and Digestive and Kidney Diseases

Participating Institutions

Clinical Centers

Barbara Davis Center for Childhood Diabetes, Denver, CO
Department of Pediatrics, University of Iowa Carver College of Medicine, Iowa City, IA
Nemours Children's Clinic, Jacksonville, FL
Division of Pediatric Endocrinology and Diabetes, Stanford University, Stanford, CA
Department of Pediatrics, Yale University School of Medicine, New Haven, CT

Coordinating Center

Jaeb Center for Health Research, Tampa, FL

Steering Committee

William Tamborlane, MD (Chair)	Craig Kollman, PhD
Roy W. Beck, MD, PhD	Linda F. Larson, RN
Keisha Bird, MSN, ARNP	Barbara Linder, MD, PhD
Jennifer M. Block, RN, CDE	Kelly L. Lofton, RN
Bruce A. Buckingham, MD	Nelly Mauras, MD
H. Peter Chase, MD	Katrina J. Ruedy, MSPH
Julie Coffey, RN, MSN, ARNP	Michael J. Tansey, MD
Sonia L. Cooper, MS, PRA	Eva Tsalikian, MD
Elizabeth A. Doyle, MSN, APRN, CDE	Stuart Weinzimer, MD
Rosanna Fiallo-Scharer, MD	Karen K. Winer, MD
Jennifer H. Fisher, ND, RN	Darrell M. Wilson, MD
Larry D. Fox, MD	Tim Wysocki, PhD, ABPP